CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Medicare Appeal Number:
1-10557152406

Exhibit A

MAXIMUS Federal

If you have questions, write or call:

Maximus Federal
DME QIC
3750 Monroe Ave
Suite 777
Pittsford, NY 14534

Telephone:
585-348-3200

Provider Inquiries

Visit: www.q2a.com

Beneficiary Inquiries

Call:

1-800-MEDICARE
Or
1-800-633-4227

Who we are:

We are Maximus Federal.
We are experts on appeals. Medicare hired us to review your file and make an independent decision.

What is the DME QIC?
The Durable Medical Equipment (DME) Qualified Independent Contractor (QIC).

L. SMITH
3590 LEXINGTON DR.
BOUNTIFUL, UT 84010-5804

December 17, 2021

RE:
Beneficiary: L. Smith
Medicare Number: XXXX-XXX-XU61
Appellant: L. Smith
Date(s) of Service: July 14, 2021

Dear L. Smith:

This letter is to inform you of the decision on your Medicare appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested a second level appeal, also known as a reconsideration, for the invasive disposable sensors (A9276).

The appeal decision is unfavorable. Our decision is that your claim is not covered by Medicare. We have determined that the beneficiary is liable. Please see below regarding further appeal rights.

More information on the decision is provided below. You are not required to take any action. However, if you disagree with the decision, you may appeal to an Administrative Law Judge (ALJ). You must file your appeal, in writing, within 60 days of receipt of this letter. The amount still in dispute is estimated to exceed the amount required to file an appeal at the ALJ Hearing level.

If this appeal is partially favorable or unfavorable, and it originated from an overpayment, the Medicare Administrative Contractor (MAC) is responsible for processing this determination in accordance with standard Medicare methodologies. Any outstanding debts, prior coverage, and prior reimbursement will be taken into account when processing this decision. The MAC will issue a demand letter containing information regarding the collection process, interest accrual, and requesting an extended repayment schedule. A copy of this letter was also sent to the supplier. Maximus was contracted by Medicare to review your appeal. For more information on how to appeal, see the page titled 'Important Information About Your Appeal Rights.'

Appeal Details at Issue

Claim Number	Supplier	Date of Service (DOS)
21200862620000	Minimed Distribution Corp.	July 14, 2021

Summary of the Facts

Initial Determination

Minimed Distribution Corp., the supplier, billed for the invasive disposable sensors (A9276) provided to the beneficiary on July 14, 2021. At initial determination, Noridian, the MAC, denied payment for the service(s).

Redetermination

A redetermination request was then submitted to the MAC. On October 6, 2021, Noridian completed the redetermination and sent a notice of their decision.

Reconsideration

The QIC received a request for reconsideration on October 20, 2021. All the information and records received by the QIC were reviewed as part of the reconsideration. Please see the 'Explanation of the Decision' section below for an explanation of our decision and how the records were used in making the decision.

Decision

We have determined that Medicare does not cover the item(s) at issue provided to you. We have also determined that the beneficiary is responsible for payment.

Explanation of the Decision

Medicare Rules

Medicare will pay for services that are reasonable and medically necessary for the diagnosis or treatment of a condition, illness or injury in the beneficiary (Social Security Act (SSA), Section 1862 (a)(1)(A)). When an appellant requests a reconsideration, all documentation to support the services being appealed must be included with the request for reconsideration. The supplier is responsible for providing sufficient documentation to support that payment is due and the services were medically necessary and provided as billed (42 Code of Federal Regulations (CFR), Section 424.5(a)(6)).

Medicare Coverage Criteria and Policies

The National Coverage Determination (NCD) for DME Reference List (280.1) states the term DME is defined as equipment which:
1. Can withstand repeated use, i.e., could normally be rented and used by successive patients;
2. Is primarily and customarily used to serve a medical purpose;
3. Generally is not useful to a person in the absence of illness or injury; and
4. Is appropriate for use in a patient's home.

The Medicare Program Integrity Manual (PIM), Chapter 5, Section 5.9, states in part for any Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) item to be covered by Medicare, the beneficiary's medical record must contain sufficient documentation of the beneficiary's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the beneficiary's diagnosis and other pertinent information including, but not limited to, duration of the beneficiary's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. However, neither a physician's order nor a Certificate of Medical Necessity (CMN) nor a DME Information Form (DIF) nor a supplier-prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. Accessory items are not separately payable when the base item is not covered.

The Local Coverage Article (LCA) for Glucose Monitors (A52464) states codes A9276 (invasive sensor for use with interstitial continuous glucose monitoring system, one unit equals a one-day supply) and A9277 (external transmitter for use with an interstitial continuous glucose monitoring system) describe the supplies used with a non-therapeutic continuous glucose monitor (CGM). Codes A9276 and A9277 are not used to bill for supplies used with code K0554.

In addition, code A9278 (receiver [monitor] for use with an interstitial continuous glucose monitoring system) describes any CGM system that fails to meet the DME Benefit requirements as described in the Centers for Medicare & Medicaid Services (CMS) Ruling 1682R.

Summary of the Rationale for the QIC Decision

The issue is whether the invasive disposable sensors (A9276) provided to you met Medicare criteria for coverage.

The decision in this case was made after all documentation was independently reviewed by a panel of clinical experts, including both a clinician and physician. It was determined that the item(s) at issue did not meet Medicare coverage criteria.

Noridian upheld the initial determination because the item billed was a non-covered item. Medicare pays for DME when it is medically necessary for use in the beneficiary's home. If the item or service is only for use outside the home, the item will be denied. NCD 280.1 further defines the term DME. Per A52464, the interstitial continuous monitoring system is a system that fails to meet the DME benefit requirements, and as such, associated supplies and accessories would not be allowed.

The PIM, Chapter 5, Section 5.9, states in part for any DMEPOS item to be covered by Medicare, the beneficiary's medical record must contain sufficient documentation of the beneficiary's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable).

The QIC reviewed this case and finds that per A52464, the base item does not meetDME benefit requirements. In addition, no medical records have been submitted for review. The QIC cannot determine if the item is used in the home or outside the home without medical records. Therefore, Medicare coverage is not allowed.

Additional Information

Medicare requires that all evidence be presented before the reconsideration is issued. On further appeal, an ALJ will not consider any new evidence unless you show good cause for not presenting the evidence to the QIC. This requirement does not apply to beneficiaries, unless a provider or supplier represents the beneficiary (42 CFR, Section 405.966).

You can receive copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision. For instructions on how to do this, please see 'Other Important Information' on the page titled "Important Information About Your Appeal Rights."

Who is Responsible for the Bill?

Because we determined that the services in question did not meet Medicare coverage criteria, under the SSA, Title 18, Section 1879, we must determine whether you and/or supplier knew or could reasonably have been expected to know that the services would not be covered under Medicare.

By statute, Medicare currently does not cover the invasive disposable sensors (A9276). The Medicare & You handbook provides advanced notice to beneficiaries of items that are not covered by Medicare. Excluded items are not covered by Medicare and therefore beneficiary liability cannot be waived. The item(s) are not payable by Medicare and therefore you are responsible for the payment of the bill (42 CFR, Section 411.15).

A supplier who believes that Medicare will deny payment for otherwise reimbursable items or services must notify beneficiaries in advance that coverage is likely to end. The Centers for Medicare & Medicaid Services (CMS) has approved documents to accomplish this and each have specific requirements that must be met (Medicare Claims Processing Manual, Chapter 30, Sections 20.1, 20.2.1, and 30.1.1).

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision

If you do not agree with this decision, you may appeal the decision to an Administrative Law Judge (ALJ) at the Office of Medicare Hearings and Appeals (OMHA). You or your representative may present your case to the ALJ at a hearing.

For ALJ Hearings filed as of January 1, 2022, the amount in controversy will remain at $180. A claim can be combined ("aggregated") with others to reach this amount if: (1) the other claims have also been decided by a QIC; (2) all of the claims are listed on your request for hearing; (3) your request for hearing is filed within 60 days of receipt of all of the QIC reconsiderations being appealed; and (4) you explain why you believe the claims involve similar or related services.

You can find more information about your right to an ALJ hearing at www.hhs.gov/omha or by calling 1-855-556-8475. This is a toll free call.

How to Appeal

To exercise your right to appeal, you must file a written request for an ALJ hearing within **60 days** of receiving this letter. If your request for hearing is being filed late, you must explain why your request is being filed late. After you file an appeal, you may check your appeal's status via the OMHA website at www.hhs.gov/omha (click on Appeal Status Lookup).

When preparing your request for hearing, please use **Form OMHA-100**, available at: www.hhs.gov/omha/forms/index.html

If you do not use the form, your request for hearing must include the following:

1. The Beneficiary's name, address, and Medicare health insurance claim number;
2. The name and address of the person appealing, if the person is not the beneficiary;
3. The representative's name and address, if any;
4. The Medicare appeal number listed on the front page of this reconsideration notice;
5. The dates of service for the claims at issue;
6. The reasons why you disagree with the QIC's reconsideration; and
7. A statement of any additional evidence to be submitted and the date it will be submitted.

You must send a copy of your request for hearing to the other parties who received a copy of this decision (for example, the beneficiary or provider/supplier). Please **do not** send a copy of your hearing request to the QIC that issued this decision or to the Medicare Administrative Contractor that issued the redetermination.

Mail your hearing request to (tracked mail is suggested):

HHS OMHA Central Operations
1001 Lakeside Avenue Suite 930
Cleveland, OH 44114-2316

OMHA processes Medicare **Beneficiary** appeals on a priority basis. If you are a Beneficiary or you represent a Beneficiary, mail your hearing request to:

HHS OMHA Central Operations
Attn: Beneficiary Mail Stop
1001 Lakeside Avenue Suite 930
Cleveland, OH 44114-2316

If you are a Beneficiary or represent a Beneficiary, you can also call the OMHA Beneficiary help line at 1-844-419-3358 for assistance. This is a toll free call. For more information on the OMHA Beneficiary prioritization program, including limitations for Beneficiaries represented by a provider/supplier, or a shared representative, visit the OMHA website at www.hhs.gov/omha or call the Beneficiary help line.

Who May File an Appeal

You or someone you name to act for you (your **appointed representative**) may file an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you.

If you want someone to act for you, you and your appointed representative must sign and date a statement naming that person to act for you and send it with your request for hearing. Call 1-800-MEDICARE (1-800-633-4227) to learn more about how to name a representative.

Help With Your Appeal

You can have a friend or someone else help you with your appeal. If you have any questions about payment denials or appeals, you can also contact your State Health Insurance Assistance Program (SHIP). For information on contacting your local SHIP, call 1-800-MEDICARE (1-800-633-4227).

Other Important Information

If you want copies of statutes, regulations, and/or policies we used to arrive at this decision, please write to us and attach a copy of this letter, at:

Maximus Federal Services
QIC Part A DME
3750 Monroe Ave., Suite KN-A9276
Pittsford, NY 14534-1302

If you have questions, please call us at the phone number provided on the front of this notice.

Other Resources To Help You

1-800-MEDICARE (1-800-633-4227),
TTY/TDD: 1-800-486-2048

1- If you need large print or assistance, call 1-800-633-4227

If you have any questions, please call the phone number on the front of this letter. For information on how to appeal this decision, please see the page entitled "Important Information About Your Appeal Rights."

Sincerely,

Danielle McPartland

Danielle McPartland
Project Director

cc:

MINIMED DISTRIBUTION CORP.
ATTN: MEDICARE APPEALS DEPARTMENT
18000 DEVONSHIRE ST.
ATTN: LEGAL DEPT.
NORTHRIDGE, CA 91325

NORIDIAN (via facsimile or electronic communication)